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EXAMINER	
OLSON, ERIC	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/030,002	CABOCHE ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-24 and 31-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-24 and 31-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted June 30, 2008 wherein new claim 38 is introduced. This application is a national stage application of PCT/FR00/01109, filed April 26, 2000, which claims priority to foreign application FR99-05523, filed April 30, 1999.

Claims 19-24 and 31-38 are pending in this application.

Claims 19-24 and 31-38 as amended are examined on the merits herein.

The following rejections of record in the previous office action are maintained:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method involving certain specific branching enzymes, for example from *E. coli*, *C. reinhardtii*, or maize, does not reasonably provide enablement for a method utilizing any possible starch branching enzyme whatsoever expressed in any genetically modified expression system whatsoever. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a

disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed method is an *in vitro* biocatalytic reaction involving a purified enzyme. In order to use the claimed invention, one skilled in the art must possess the branching enzyme.

The state of the prior art: Various starch branching enzymes are known in the art from various organisms. In fact, these enzymes are common across a wide variety of species due to the ubiquity of starch as a storage medium. Some of these enzymes have been cloned and recombinantly expressed, and are useful for modifying the properties of starch *in vitro*. For example, enzymes from maize, *Bacillus megaterium*, and *Chlamidomonas reinhardtii*, have been isolated in this manner. However, the prior art does not reveal the isolation of each and every possible starch branching enzyme, or of a representative sample thereof.

Furthermore, while certain expression systems such as *E. coli*, yeast, or mammalian cell culture are well known in the art for expressing recombinant proteins, the prior art does not reveal the full scope of all possible genetically modified organisms

that could be used to express an exogenous protein such as a starch branching enzyme.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: Discovering new genes in new organisms is an unpredictable task. Although one skilled in the art would have reason to suspect that many organisms possess an as yet undiscovered starch branching gene, finding that gene in the genomes of a wide variety of plants and microorganisms would involve difficult and unpredictable experimentation. Furthermore, the expression and purification of an enzyme, which is necessary in order to use it in the claimed method, is also difficult and unpredictable. According to Short Protocols in Molecular Biology, Third Edition, (Reference included in PTO-892) bacterial expression systems have several disadvantages, including lack of post-translational modification, formation of inclusion bodies, and inadequate excretion from the cell. Mammalian and baculoviral expression systems can overcome some of these disadvantages but are more difficult and time-consuming and are not adequate for the large-scale production of proteins. Each new starch branching enzyme would require further experimentation to determine the best method for expression and purification before it could be used in the claimed method.

Furthermore, in order to use any "genetically modified organism capable of expression said enzyme," one skilled in the art would have to develop a wide variety of recombinant expression systems involving a large number of unrelated organisms

and tissue cultures. This process would be highly unpredictable as many organisms are not well characterized and their suitability for protein expression is not known.

Therefore the process of obtaining every starch branching enzyme would be highly unpredictable.

The Breadth of the claims: The claimed invention is very broad, encompassing all starch branching enzymes. There is no particular limitation on the species from which the enzyme is extracted or its structural or physical properties.

The amount of direction or guidance presented: The claimed specification suggests the use of certain existing starch branching enzymes. In addition, a general strategy is suggested for the use of polyclonal antibodies to discover new enzymes related to existing algal starch branching enzymes.

The presence or absence of working examples: The working examples provided use one specific enzyme, obtained from *Chlamidomonas reinhardtii*.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the discovery, purification, and expression of new enzymes. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the full scope of the invention with every possible starch branching enzyme, one skilled in the art would have to identify a vast range of different enzymes, and express and purify them in a form suitable for use. Because the prior art does not teach expression and purification of every possible enzyme, many of these techniques would have to be developed from

scratch. Although some of these enzymes have been successfully used for *in vitro* biocatalysis, finding optimal expression and purification methods for all of the remaining enzymes would be difficult and unpredictable as discussed above. Furthermore, using all possible genetically modified organisms as expression systems would provide an equally great and unpredictable burden of experimentation. Therefore practicing the full scope of the invention would require an undue burden of unpredictable experimentation.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the lack of guidance or working examples and the unpredictability of the art, Applicants fail to provide information sufficient to practice the claimed invention for all possible enzymes and expression systems.

Response to Argument: Applicant's arguments, submitted June 30, 2008, with respect to the above ground of rejection have been fully considered and not found persuasive to remove the rejection. Applicant argues that the claims are not drawn to the discovery of new branching enzymes. However, because the claims encompass methods involving any possible branching enzyme, practicing the full scope of the claimed invention would necessarily require the use of a wide variety of novel branching enzymes. One skilled in the art would have to discover these enzymes in order to

practice the invention. While some species of branching enzyme are conventional and easily obtainable, for example *E. coli* branching enzyme, many others are not.

All proteins exist in many different forms in different species of organisms. Although homologous enzymes are similar, they are not the same product. The enzymatic sequence will differ between species and as a result selectivity or kinetic parameters of the enzyme will vary. Isolation of an enzyme from a handful of species does not enable the isolation of every similar enzyme from every species in existence. Applicant's references serve to demonstrate that this class of enzyme is known, but does not serve to demonstrate that one skilled in the art could obtain every variant of the enzyme.

Furthermore, Applicant argues that the skilled artisan would be able to obtain any conventional branching enzymes without undue experimentation. Firstly, the word "conventional" appears nowhere In the claim language. Secondly, even if it did, it is too indefinite to clearly and distinctly limit the claims to a particular set of enzymes that one skilled in the art would be able to easily obtain. Thirdly, there are millions of different species in existence. Practically all of these species store energy as glycogen or starch and thus possess a branching enzyme to synthesize branched glucose polymers. Most species have not been identified and classified. Even fewer can be raised or cultured in captivity under conditions that would allow one skilled in the art to isolate the branching enzyme. Furthermore it is noted that finding a specific gene in an unsequenced genome is a difficult, unpredictable process that involves undue experimentation.

Isolating and purifying a native protein from an organism that is not a well characterized expression system is similarly difficult and unpredictable.

For these reasons the rejection is deemed proper and made **FINAL**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19-22 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (US patent 4454161, of record in previous office action) in view of Senkeleski et al. (US patent 5562937, cited in PTO-892) Okada et al. discloses a branched alpha-glucose polymer (starch) produced by the activity of a branching enzyme, for example an animal, plant, or microorganism branching enzyme in a starch such as amylopectin. (column 1 lines 47-63) A gelatinized solution of the starch is subjected to the action of the branching enzyme and then used, after concentration and/or drying, in food products. (column 2, lines 5-20) A bacillus branching enzyme is reported (column 5, lines 15-23) having an optimal temperature of about 25C and being stable up to about 45C. (column 6 lines 39-49) an *E. coli* branching enzyme is also reported. (column 8 lines 1-25) These starches display a reduced propensity for retrogradation. (column 2, lines 21-31) Okada et al. does not disclose a method in which

the starch is gelatinized by a treatment at over 130°C and 3.5 bars as recited in the instant claims. Okada et al. also does not explicitly disclose a method in which the amount of branching enzyme is between 50-2000 units and the reaction is carried out at exactly 30°C.

Senkeleski et al. discloses a method for digesting waxy starch with beta-amylase. (column 1, lines 40-58) The starch, in order to be processed in this manner, is first steam cooked at a temperature of 120°C to 170°C at a pressure of 60-80 psi, which is equivalent to about 4.1-5.5 bar.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the gelatinization process of Senkeleski et al. to pre-gelatinize the starch, for example amylopectin, before the enzymatic step of Okada et al. using a bacillus or *E. coli* branching enzyme. One of ordinary skill in the art would have been motivated to use this gelatinization step because Okada et al. already teaches the use of a gelatinization step before the enzymatic digestion, and because the gelatinization of Senkeleski et al. is shown to be useful for gelatinizing starch in preparation for enzymatic digestion. One of ordinary skill in the art would reasonably have expected success because gelatinization procedures are routine and well known in the art, and choosing an appropriate procedure would be well within the ordinary and routine level of skill in the art.

Furthermore, it would have been obvious to one of ordinary skill in the art to optimize the amount of branching enzyme, and reaction temperature and duration to arrive at the values discussed in the instant claims. One of ordinary skill in the art would

have been able to choose optimal values for these experimental parameters through a simple process of routine optimization, and would clearly have recognized reaction time, temperature, and amount of catalyst to be result-effective variables that could be varied to produce the desired result.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted June 30, 2008, with respect to the above ground of rejection have been fully considered and not found persuasive to remove the rejection. Applicant argues that Senkeleski et al. discloses a gelatinization step meant to gelatinize starch in preparation for digesting it into smaller subunits while Okada et al. and the present invention disclose a method of gelatinizing starch in preparation for adding branches to the starch. It is not clear from Applicant's argument what the difference between the two **gelatinization** steps is. The combination of the two references does not depend on combining the branching step with the hydrolysis step. Rather the only element taken from Senkeleski et al. is the gelatinization, which merely prepares the starch for enzymatic reaction and is not dependent on one particular enzymatic reaction. It is a conventional method for jet-cooking starch which would be recognized by one of ordinary skill in the art as being useful for gelatinizing starch for a wide variety of purposes. Gelatinization is well known in the art and methods of gelatinization do not depend in the intended use of the gelatinized product. Okada et al. does not limit the invention to one particular gelatinization method either but merely requires a gelatinized starch. One of ordinary

skill in the art would have obtained this starch by conventional gelatinization methods, of which the gelatinization disclosed by Okada et al. is one.

For these reasons the rejection is deemed proper and made **FINAL**.

Claims 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (US patent 4454161, of record in previous office action) in view of Senkeleski et al. (US patent 5562937, cited in PTO-892) as applied to claims 19-22 above, and further in view of Sandström et al. (PCT international publication WO95/22562, reference included with PTO-1449, also published as Brynolf et al. (US patent 5929052, cited in PTO-892) The disclosures of Okada et al. and Senkeleski et al. are discussed above. Okada et al. and Senkeleski et al. do not disclose a composition having the characteristics described in instant claims 31-37.

Sandström et al. discloses a branched starch (alpha-glucose polymer) having a molecular weight ranging from $1.5x10^4$ to 10^7 daltons, corresponding to the limitations in instant claim 31. (p. 3, lines 16-24) These starches have a branching degree of about 2-8%, preferably 3-7%. (p. 4, lines 1-3) A starch with this molecular weight will possess less than 1% reducing sugars, as there will be only one reducing end per molecule. The starch is particularly stable in solution, (p. 2 lines 25-31) and will therefore have a low tendency to retrograde in solution. These molecules are also considered to possess the claimed viscosity of at most 5000 cP in view of the fact that they possess the same structural characteristics (size, degree of branching) as those described in the instant specification. (for example p. 21, table II of the instant specification) It is noted

that the starches of Sandström et al. differ from the claimed invention in that they possess beta-glycosidic linkages as a result of the specific method of acid treatment used to increase the branching degree.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the method of Okada et al. in view of Senkeleski et al. to produce a branched product as described by Sandström et al., having the same molecular weight and degree of branching but lacking beta-glycosidic bonds. One of ordinary skill in the art would have recognized that the enzymatic treatment of Okada et al. in view of Senkeleski et al. produces the same result, namely increased branching, as the acid treatment of Sandström et al., and that the two treatments are therefore interchangeable. With regard to the presence of beta-glycosidic bonds in the compounds of Sandström et al., this structural feature is an incidental result of the particular acid treatment used, and is not seen to be necessary for the desired properties, namely stability and reduced osmolality, present in the starches of Sandström et al. One of ordinary skill in the art would reasonably have expected success because the method of Okada et al. in view of Senkeleski et al. is already seen to be useful for increasing the branching degree of a starch.

Furthermore, it would have been obvious to one of ordinary skill in the art to optimize the various characteristics of the starch of Sandström et al., such as degree of branching and molecular weight, to arrive at the values discussed in instant claims 32, 36, and 37. One of ordinary skill in the art would have been able to choose optimal values for these experimental parameters through a simple process of routine

optimization, and would clearly have recognized these structural properties to be result-effective variables that could be varied to produce the desired solution properties in the final product.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted June 30, 2008, with respect to the above ground of rejection have been fully considered and not found persuasive to remove the rejection. Applicant argues that Sandström et al. discloses a method that produces a product having beta-glycosidic linkages while the claimed invention requires that there be no beta-glycosidic linkages. The beta-glycosidic linkages are not important to the functionality of the starch of Sandström et al., which is intended as a dietary carbohydrate source. They are only present because of the chemical method (acid treatment) used to prepare the starch. One of ordinary skill in the art would expect enzymatically branched starch prepared according to Okada et al. in view of Senkeleski et al. to be equally useful as a carbohydrate energy source. Therefore one of ordinary skill in the art would be motivated, upon viewing the disclosure of Sandström et al., would be motivated to produce a starch having the specific molecular weight and branching degree, and incidentally reducing sugar content as disclosed by Sandström et al. This could be accomplished by the chemical method disclosed by Sandström et al., resulting in a product with beta-glycosidic linkages, or it could also be accomplished by the enzymatic method of Okada et al., which would result in a starch according to the claimed invention.

Therefore the rejection is maintained and made **FINAL**.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of US patent 7015318. (Cited in PTO-892, herein referred to as '318) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-4 of '318 anticipate the claimed invention. These claims are drawn to a method wherein a starch is gelatinized under heating, cooled, and treated with a branching enzyme. According to claims 3-4 these enzymes are introduced at between 20-70 C, and include starch branching enzymes. While the language used in the claims is somewhat generic, the specification of '318 further defines the gelatinization step as involving heating the

starch to between 110-170C, and the branching enzyme as being extracted from higher plants, yeasts, bacteria, and algae. (column 4, lines 33-38) Example 1 (column 6, lines 15-65) discloses an experimental method falling within the methods of instant claims 19-21 and producing products B and C identical to instant claims 31-37. Therefore the claims 1-4 of '318 are properly interpreted as including gelatinization and digestion steps falling within the limitations of instant claims 19-22.

Furthermore, it would have been obvious to one of ordinary skill in the art to optimize the amount of branching enzyme, and reaction temperature and duration to arrive at the values discussed in the instant claims. One of ordinary skill in the art would have been able to choose optimal values for these experimental parameters through a simple process of routine optimization, and would clearly have recognized reaction time, temperature, and amount of catalyst to be result-effective variables that could be varied to produce the desired result.

Response to Argument: Applicant has offered no arguments traversing the merits of this rejection. Therefore it is made **FINAL**. It is noted that the previous office action identified the rejection as a provisional rejection. However, the rejection is clearly a nonprovisional rejection as it was made over an issued patent.

Conclusion

No claims are allowed in this application. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
9/2/2008

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623